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what other ingredients which could be added, one of ordinary skill in the art would presume that in an **oil-in-water emulsion** an oil phase and water phase would be present. Especially given that the applicants have not indicated a definition of "oil-in-water emulsion" which is contrary to its normal meaning.

The claim has been amended to incorporate the phrase "oil phase and water phase and:". However, this amendment is redundant and was not necessary. The scope of the applicants claim has not changed by this amendment.

(Note for examiner: Had there been a basis for the omission of an oil phase and water phase, it would've been more appropriate to reject under 35 U.S.C. 112, second paragraph (essential elements omitted – see form paragraph 07-34-13), not 112, first paragraph. In any event, the applicants response above would've been essentially unchanged.)

35 U.S.C. 103(a) rejection

Claims 1-3 and 6-11 were rejected by the examiner as being obvious over Ascione et al. (U.S. Patent 5,858,334) in view of Gohla et al. (U.S. Patent 5,750,124)

Claims 4 and 5 were rejected by the examiner as being obvious over Ascione et al. and Gohla et al., *ibid.* and further in view of Muller et al. (U.S. Patent 4,719,239).

The applicants request reconsideration of both rejections for the following reasons.

There are additional differences between Ascione et al. and the applicants' claimed invention than those cited by the examiner

The only difference between the Ascione et al. reference and the applicants' claimed invention as ascribed by the examiner is that "Ascione lacks specific teachings on the properties of emulsifiers". However, the applicants assert that when making the "as a whole" consideration (see MPEP 2141.02) of Ascione et al. and the applicants' claimed invention, there are several other features of their invention which distinguish it from the applicants' claimed invention.

Ascione et al. is directed toward emulsions which are constrained by various critical limitations/essential features. These include:

- (a) The average size of the particles or globules of the fatty phase of Ascione et

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- al. "must fall within very specific limits, namely ranging from 100 nm to 1,000 nm" (see col.3, lines 15-19);
- (b) The emulsions of Ascione et al. contain dihydroxyacetone (DHA) which greatly complicates and limits the types of emulsifying agents which can be selected (see col. 4, especially lines 32-34 which states "One of the difficulties in carrying out a process as described above is in the selection of the emulsifying system, which must be suited to the desired result." and lines 41-63 which describe the limited scope of emulsifiers suitable for Ascione et al.'s invention.
- (c) With regard to karite butter, Ascione et al. discloses it amongst a large Markush group of potential ingredient which may comprise the fatty phase (see col. 2, line 38 thru col. 3, line 9); it is not present in any of the examples cited in Ascione et al. Moreover, Ascione et al. does not describe the inclusion of karite butter in the applicants claimed amounts (i.e. "an effect amount to reduce the stickiness/greasiness of the oil-in-water emulsion').

Gohla et al. taken in view of Ascione et al. does not remedy the differences within Ascione et al. and does not teach or suggest the applicants claimed invention

No reasonable expectation of success when combining teachings of Gohla et al. with Ascione et al.

The Gohla et al. reference was relied upon by the examiner to show emulsifiers which are possibly within the scope of those described in the applicants' claimed invention. However, col. 2, lines 55-63 of Ascione et al. states:

"Moreover, also preferably, the emulsifier system selected will possess an overall HLB...ranging from approximately 9.5 to 11.5, advantageously close to 10, such as to permit a phase inversion to be attained at a temperature of less than 90°C..."

Gohla et al. teaches that their emulsifiers have an HLB of between 11 and 18 which is outside the preferred range of emulsifiers which are critical to the Ascione et al. reference to permit a phase inversion, i.e. there is no reasonable expectation of success to combine the teachings of Gohla et al. with Ascione et al. as the former reference suggests the use of emulsifiers which are incompatible with the invention of Ascione et al.

Furthermore, given the critical limitations of Ascione et al.'s invention, there is no reasonable expectation of success to substitute the use of emulsifiers of Gohla et al. while keeping the

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average particle/globule size of the fatty components of Ascione et al. within the prescribed ranges and that the emulsifiers of Gohla et al. would be compatible with the DHA of Ascione et al.'s invention especially when considering that the emulsifiers used in Gohla et al. are for a W/O/W emulsion whereas the applicants' claimed invention and that of Ascione et al. are O/W emulsions.

Improper to pick and choose elements

It has previously been held that **"[i]t is impermissible** within the framework of section 103 **to pick and choose** from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." (see *In re Wesslau*, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965))

More recently, it has been held that **"... 'Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.' see *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546, 48 USPQ2d 1321, 1329 (Fed. Cir. 1998).**

There must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor. see *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 665, 57 USPQ2d 1161, 1167 (Fed. Cir. 2000); *ATD Corp.*, 159 F.3d 546, 48 USPQ2d 1329; *Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc.*, 21 F.3d 1068, 1072, 30 USPQ2d 1377, 1379 (Fed. Cir. 1994) ('When the patented invention is made by combining known components to achieve a new system, **the prior art must provide a suggestion or motivation** to make such a combination.')

see *Crown Operations Int'l., Ltd. v. Solutia, Inc.*, 289 F.3d 1367, 62 USPQ2d 1917 (Fed. Cir. 2002).

In the present situation, the Gohla et al. reference was selectively relied upon for their choice of emulsifiers to the exclusion of the other ingredients which constituted their W/O/W emulsions and the Ascione et al. was selectively relied upon (among other reasons) for the choice of karite butter out of a Markush group of fatty components without a description of the the applicants claimed amounts (i.e. "an effect amount to reduce the stickiness/greasiness of the oil-in-water emulsion").

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Motivation to combine references is from examiner's assertion, not the prior art

MPEP 2143 states that "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)" MPEP 2143.01 also establishes that "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)".

The examiner's stated motivation for combining Gohla et al. with Ascione et al. was "...because of the expectancy of producing composition systems which are stable microscopically over relatively long storage times or in a wide temperature range or towards extreme variations in temperature." However, neither the Gohla et al. or Ascione et al. references teach or suggest such a benefit if the Gohla et al. teachings were substituted into Ascione et al. The examiner appears to be making this presumption and given the incompatibilities of the two references as described above (i.e. it is unclear that the reference even can be combined), such a presumption cannot be made. If the examiner was taking official notice for her statement of motivation, the applicants' now formally request that a reference be provided which affirms her hypothesis.

All claim limitations not taught

With regard to the dependent claims 3, 8 and 9, the examiner is reminded that MPEP 2143.03 states that "To establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." (see also *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)). As the applicants have argued above that neither Ascione et al. or Gohla et al. teach the selection of shea butter in an amount to reduce stickiness/greasiness of an oil-in-water emulsion, it further follows that neither Ascione et al. or Gohla et al. teach the specific amounts of shea butter as used in these claims.

Muller et al. does not remedy the deficiencies of Ascione et al. in view of Gohla et al.

Even if Ascione et al. in view of Gohla et al. had rendered claim 1-3 and 6-11 obvious, the inclusion of Muller et al. would not overcome the differences set forth in claims 4 and 5 of the applicants' invention.

First, the compositions of Muller et al. are directed toward enhancing the penetration of a pharmaceutical active agent through the skin (see col. 3, lines 1-3) not reducing the stickiness/greasiness of the emulsion.

While the motivation for modifying the reference does not have to be the same as the applicants intended use, it has not been established that modifying Ascione et al. and Gohla et al. as directed by Muller et al. intended effect would achieve the applicants' emulsions, i.e. no reasonable expectation of success.

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Second, the use of coemulsifiers in Muller et al. is contingent upon "special properties of the systems according to the invention (which) are based on the use of certain surfactant/cosurfactant combinations" (see col. 3, lines 35-37). Moreover, the disclosure of Muller et al. that "The nature and concentration of the coemulsifiers of the surfactant and cosurfactant determine both the scope of the thermodynamic, stable, single-phase range and also the viscosity of the system and the temperature range in which there is thermodynamic stability" (see col. 4, lines 33-37) merely represent an invitation to experiment; i.e. one of ordinary skill in the art would undergo undue experimentation to arrive at the applicants invention without the benefit of the applicants teachings.

Lastly, Muller et al. discloses that their multicomponent system is effected by the nature of the dissolved active agent and as such represents a critical element of their invention (see col. 4, line 66 thru col. 5, line 5) and as such cannot be ignored when determining the substitution of their teachings to that of Ascione et al. and Gohla et al.

Closing

Applicants believe that this application is in condition for allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.111 (7 pages total) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: 18 October 2002

By: Vilma I. Fernandez

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